## APPENDIX 6 – CDC FORM 50

Justification must be completed by State health of before specimen can be accepted by CDC. Please chattement and when appropriate complete the statem.  1. Disease suspected to be of public health importan. (a)   from an outbreak. (b)   from an outbreak. (c)   an isolate that cannot be identified, is atyganibilotic resistance, or from a normally state of the promain of the promai	eck the first applicable nent with the *. co. Specimen is: bical, shows multiple erile site(s). c reagents or expertise	STATE HEALTH DEPA	ARTMENT L	ABORATOR	Y ADDRES	Si
2. Ongoing collaborative CDC/ State project. 3. Confirmation of results requested for quality assurance. Please bring to the attention of: (Name)	Completed by:	STATE HEALTH DEPT, NO.: PATIENT IDENTI	FICATION	DATI TO (	CDC:	onth Day Year
Name, Address and Phone Number of Physician or C	Organization:	NAME: Last (18-37)	FI	irst (38-47)		Aiddle Initial (48)
		BIRTHDATE: (49-54)	Month	Day	Year	SEX: (55)
		CLINICAL DIAGNOSIS:				(56-57)
(For CDC Use Only) CDC NUMBER DATE RECEIVED(12-17)		ASSOCIATED ILLNESS:				(58-59)
UNIT FY 3-4) NUMBER (5-10) SUF (11)		DATE OF ONSET (Mo				TAL? (66) YES NO
REVERSE SIDE OF THIS FORM	MUST BE COMPLETED	Typ	e Specimer	30.000.000.0001000		

## THIS FORM MUST BE EITHER PRINTED OR TYPED PLEASE PREPARE A SEPARATE FORM FOR EACH SPECIMEN

D.A.S.H. Date Reported 0 3 (14-19) Comments:

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Central
Center for Infectious Disease
Atlanta, Georgia 30333



LABORATORY EXAMINATION(S) REQUESTED (31-36)  Antimicrobial Susceptibility   IDentification   SErology (Specify Test)	
☐ Histology ☐ (Specify) ☐ OTher (Specify)	
CATEGORY OF AGENT SUSPECTED (37) Bacterial Viral Fungel Ricket	sial Parasitic Other (Specify)
	R ORGANISM(S) FOUND: (41-46)
ISOLATION ATTEMPTED? (47) Yes No NO. TIMES ISOLATED (48-49)	
SPECIMEN SUBMITTED IS (52). Original Material Pure Isolate Mixed Isolate	
DATE SPECIMEN TAKEN (53-58) ORIGIN (59-60)	ANimal (specify)
_,,,,,	OTher (Specify)
SOURCE OF SPECIMEN (61-62): BLood GAStric SErum SPutum UR	
□ WOund (Site)	Tissue (Specify)
EXudate (Site)	OTher (Specify)
SUBMITTED ON (63-64): MEdium (Specify)	g cred commentified
ANimal (Specify)	CLINICAL TEST RESULTS: (12-13) 0 2
SERUM INFORMATION: Mo. Da. Yr.	Sputum and Histological Findings
(73-80) COnvelercent	Blood Counts Urine Exams
(81-88) 🗆 53	Type Skin Tests PerformedMo, Da Strength Pos. Neg.
(89-96) S4	(14-21)
(97-104) ☐ \$5	(23-30) (33)
IMMUNIZATIONS: Mo. Yr.	
(111-1)	(104-49) FEver (104-105) Headache
(117-12	
(123-120	(110-111) Hydrocephalus
TREATMENT: Drugs Used None (129) Date Begun Date Completed Mo, Da, Yr. Mo, Da, Yr.	RASH: (112-113) Li SEizures
(130-14	
(144-15	) (62-63) 🗆 VEsicular (118-119) 🖵 PAralysis
(158-17	) (64-65) ☐ Erythema Nodosum (120-121) ☐ OTher (66-67) ☐ Erythema Marginatum MISCELLANEOUS:
EPIDEMIOLOGICAL DATA: (172-173)	(68-69) OTher (122-123) Aundice
SIngle Case SPoradic COntact EPidemic CArrier	RESPIRATORY: (124-125) MYalgia
Family Illness (174-175) Community Illness (176-177)	(70-71) ☐ RHinitis (126-127) ☐ PLeurodynia (72-73) ☐ PUlmonary (128-129) ☐ COnjunctivitis
Travel and Residence (Location)Mo. Yr.	(74-75) PHaryngitis (130-131) CHorioretinitis
□ Foreign(178-163)	(76-77) CAlcifications (132-133) SPlenomegaly
USA(184-189)	(78-79) ☐ PNeumonia (type) (134-135) ☐ HEpatomegaly (80-81) ☐ OTher (136-137) ☐ Liver Abscess
Animal Contacts (Species)(190-191)	CARDIOVASCULAR: (138-139) LYmphadenopathy
Arthropod Contacts: (192) None Exposure Only Bite	(82-83) MYocarditis (140-141) MUcous Membrane Lesion (84-85) PEricarditis (142-143) OTher
Type of Arthropod	(86-87) ☐ ENdocarditis STATE OF ILLNESS:
	GASTROINTESTINAL: (144-145) ☐ SYmptomatic
PREVIOUS LABORATORY RESULTS/OTHER CLINICAL INFORMATION: (Information supplied should be related to this case and/or specimen (s)	GASTROINTESTINAL: (146-147) Asymptometic (190-91) Distribes (148-149) Subscute
and relative to the test (s) requested.	(92-93) 🔲 BLood (150-151) 🛄 CHronic
	(94-95) ☐ MUcous (152-153) ☐ Disseminated (96-97) ☐ COnstipation (154-155) ☐ LOcalized
	(98-99) ABdominal pain (156-157) Ntraintestinal
	(100-101) O VOmiting (158-159) EXtraintestinal
	(102-103) OTher (160-161) OTher
FOR CDC USE ONLY 0 1 (12-13) No. Specimens: (16-20)	No. Tests: (21-25)
TYPE SERVICE: (14-15) LOCATION CODE: (26-27)	SPECIMEN SUBMITTED BY: (28-30)
	NU Nicaragua SZ Switzerland 100-Health Dept. 323-Indian Hosp.
02-Epid, Aid AS Australia CO Colombia HA Hatti 03-Proficiency Testing AU Austria CS Costa Rica HO Honduras 04-Spacial Replacts BC Bermuda CY Cyprus IN India	VZ New Zelaned TD Trinided-Tobago 200-CDC Clinic 322-NIH 322-NIH 400-Foreign TH Thailand 200-Proficiency Testing 400-Foreign or part of the Section 200-Proficiency Clinic 500-Proficiency Clinic 500-Proficency Clinic 500-Prof
O1-Reference AR Argentina CM Cameroon OT Gustemala O2-Epid. Aid A Australia CO Colombia HA Hatia O3-Proficiency Testine BE Bergium DR Dominican Rep. IS Israel O4-Special Projects BE Bergium DR Dominican Rep. IS Israel O4-Dother BL Bolivia ES Et Salvador IT Itlay BR Brazil ES ET Salvador JM Jamaica	VI Nicaragua S. Switzerland 100-Heatth Dept. 322-Indian Hosp. 322-New Zelanad TO Trindad-Tobago 200-CDC Clinic Plant 100-Heatth Dept. 322-New Zelanad TO Trindad-Tobago 200-CDC Clinic Plant 100-Heatth Dept. 322-New 200-CDC Clinic Plant 100-Heatth Dept. 322-New 200-Heatth
Other BR British Honduras E.S. Ettagodor IV Isony Coast BR Brasil ET Ethloplu JM Jamaica G.A. Canada FR France MX Mexico CB Cambodia GE Germany MV Malayila	N Panama UY Uruguay 303-Air Force P New Guines VE Venezuela 307-V.A. Hosp.
01-Reference AR Argentina CM Cameroon GT Gustemale CP-Did, AND AS Australia CO Colombia HA Hatti O3-Proficiancy Testine AU Austria CS Costa Rica HO Honduras BE Belgium DR Dominican Rep. 15 Israel BH British Honduras CS Could Find Rep. 15 Israel CS Costa Rica HO Honduras CS COSTA RICA HO HONDURAS CS COUNTING REP. 15 Israel CS COSTA RICA HO HONDURAS CS COUNTING REP. 15 Israel CS COSTA RICA HO HONDURAS CS COUNTING REP. 15 Israel CS CS COSTA RICA HO HONDURAS CS COUNTING REP. 15 Israel CS CS COSTA RICA HO HONDURAS CS COUNTING REP. 15 Israel CS	NU Niceragua Z Switzerland 100-relatin Dopt. 323-indian Hosp. 325-New Zeland TD Triinded-Tobego Peru TW Talaind TD 200-CDC CInnic 200-CDC Cin
CI CRIE GQ GUAM NI NIGOTIA	P Spain Late Other
CDC 50.34 REV. 11-90 (BACK)	UNIT   FY   NUMBER   SUF.
(Formerly 3.203)	CDC NUMBER
*U.S.GPO:1996-734-363	

# APPENDIX 7 – CDC CONSENT FORM: SARS-COV REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT-PCR) TESTING



## SEVERE ACUTE RESPIRATORY SYNDROME

CDC IRB approval as of 2/6/04

## Consent Form (SARS Laboratory Testing Public Health Response): Reverse Transcription Polymerase Chain Reaction (RT-PCR) Testing

The Centers for Disease Control and Prevention (CDC) and public health laboratories are using an investigational laboratory test to test for the virus that causes "severe acute respiratory syndrome" or (SARS). The Food and Drug Administration (FDA) has not licensed this test. The FDA has agreed that we can use this test under an investigational device exemption (IDE). We don't know for sure if this test can find all people who may get sick with SARS. There are no FDA approved tests that quickly find the virus.

Your State or Local Health Department and CDC are using the results of this test as one piece of information to help us find out if people are sick with SARS and to limit the spread of this illness. Your (or your child's) doctor will use other information along with this test result to decide what is best for you (your child).

#### BACKGROUND

SARS is a respiratory illness that can start as fever and cough. It may go on to pneumonia in some people. SARS seems to be spread by close person to person contact. This can occur when a person who is sick with SARS coughs or sneezes onto themselves, other people, or nearby surfaces. Droplets from the cough or sneeze can travel a short distance through the air and land on the mouth, nose, or eyes of persons who are nearby. The virus also can spread when a person touches a surface or object with infectious droplets and then touches his or her mouth, nose, or eye(s). It also is possible that SARS can be spread through the air or by other ways that we don't yet know about.

#### WHY SHOULD MY (MY CHILD'S) SAMPLE BE TESTED?

You (or your child) may be asked to have SARS testing done when there are no reported cases of SARS in the world or when and if SARS returns. It is important to test for SARS when there are no reported SARS cases so that public health efforts could quickly identify a case and limit its spread. The results of this test, along with other information, may also help your (your child's) doctor take better care of you (your child). You (or your child) may be asked to be tested for the SARS virus because:

- You (or your child) are being hospitalized for symptoms like pneumonia and within 10 days of the start of symptoms you (or your child):
  - a. Have traveled to an area that had reported SARS cases in the past, or
  - b. Had close contact with an ill person who just came back from these areas, or
  - Had close contact with person(s) who have pneumonia like symptoms and have not been diagnosed, or
  - d. Are employed in a job that may put you at risk for SARS, such as a healthcare worker with direct patient contact or a worker in a laboratory that has live SARS virus.

#### OR

- There are reported cases of SARS in the world and you (or your child) have symptoms which may be early symptoms of SARS, such as fever or lower respiratory symptoms or other symptoms your doctor feels might be SARS and:
  - a. Recent close contact with persons thought to have SARS, or

February 6, 2004

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
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## Consent Form (SARS Laboratory Testing Public Health Response): Reverse Transcription Polymerase Chain Reaction (RT-PCR) Testing

(continued from previous page)
CDC IRB approval as of 2/6/04

 Recent exposure to areas (in the U.S. or outside the U.S.) with confirmed or suspected SARS (or close contact with ill persons with a history of these exposures)

#### ARE THERE ANY BENEFITS?

There may be no direct benefits to you (or your child) from having this test done. This test may help to find the virus in people who do not yet have all the signs of SARS. If people with the SARS virus limit contact with other people, this can prevent others from getting sick. By having this test done, you may lower the chance of spreading the virus from you (your child) to your family or others. Use of this test could also help us to know more about this virus to help stop the spread of this illness. The results of this test, along with other information, may help your (your child's) doctor take better care of you (your child).

#### IF THIS TEST IS POSITIVE, DOES THAT MEAN I (MY CHILD) HAVE SARS?

There is a small chance that this test may give a positive result for the SARS virus when the virus is not there (false positive). If your (your child's) result from this test is positive:

- You (your child) could be asked to limit contact outside the home by not going to work, school, out-of-home childcare, church, or other public areas. You may also be asked to use a mask at home to limit the risk of spread of the virus. If you (your child) have had symptoms of SARS, you might be asked to follow these limits because of these symptoms and not because of the test results. If your (your child's) tests are positive, there is a small chance that you (your child) may be asked to follow these limits even if you (your child) do not seem sick.
- There is no proven treatment for SARS at this time. If you (your child) your child is very ill, in rare cases, you (your child) may be advised to take an antiviral drug. If this happens, your (your child's) doctor will discuss the risks and benefits and obtain your consent.
- Your (or your child's) doctor may decide how to care for you based on the test results along with other factors.

#### IF THIS TEST IS NEGATIVE, DOES THAT MEAN I (MY CHILD) DO NOT HAVE SARS?

This test may give a negative result when you (or your child) do have the virus (false negative). A false negative result should not effect your (or your child's) care. CDC has told doctors that a negative test alone does not prove that a person does or does not have the SARS virus. No changes in your medical care or how you interact with other people should be based on a negative result.

#### ARE THERE ANY RISKS FROM TAKING MY (MY CHILD'S) SAMPLES?

To do this test, extra samples may be taken that are like samples that are normally taken for testing when you are sick. Your (your child's) doctor may also ask to take more samples in the future. These samples may include nasal swab or aspirate, throat swab, sputum, blood, serum, plasma or stool.

The nasal swabs are taken by placing one small swab into the back of your (or your child's) nose for 5 seconds. The throat swabs are taken by placing one small swab into the back of your (or your child's) throat for 5 seconds. A nasal aspirate may also be done by placing 1-2 cc (less than  $\frac{1}{2}$  teaspoon) of salt water into each side of your (or your child's) nose and then removing it after a few seconds. These tests don't hurt, but may cause a little discomfort. Rarely, they make people gag, cough or get a bloody nose.

Sputum is taken by asking you (or your child) to cough deeply and to spit the sputum into a cup. There is no risk to (or your child) when sputum is taken.

If a broncheoalveolar lavage (BAL) is needed this will be explained to you by your doctor. Your doctor will explain the risks and the procedure in detail and obtain your consent.

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#### Consent Form (SARS Laboratory Testing Public Health Response): Reverse Transcription Polymerase Chain Reaction (RT-PCR) Testing

(continued from previous page) CDC IRB approval as of 2/6/04

When blood is taken you (or your child) may feel a slight sting or "pinch" in your (or your child's) arm. You (or your child) might also get a small bruise from the needle. Rarely, some people faint. There is also a very small risk of an infection any time that blood is taken.

There is no risk to you (your child) when stool is taken.

#### ARE THERE OTHER CHOICES?

There are no other rapid laboratory tests approved by FDA that can be used to tell if you (or your child) have the virus believed to be causing SARS.

#### WHAT ABOUT PRIVACY?

We will keep all facts about you (your child) as private as the law allows. CDC, FDA, the Local/State Health Department staff and the person(s) who ordered your test (such as your Doctor) may see your/your child's results. When we present or publish papers about these tests, neither you (nor your child) will be named.

#### WHAT ARE THE COSTS?

The test will be done by CDC or your health department at no cost. You, your insurer, Medicare or Medicaid will need to pay for other costs related to the testing, such as Doctor's visits.

#### WHAT HAPPENS IF YOU (YOUR CHILD) ARE HARMED?

If you (your child) are harmed as a result of taking the samples, CDC will not pay the costs for hospital and medical care. You, your insurer, Medicare or Medicaid will need to pay those costs. You (or your child) do not give up any legal rights that otherwise would be available to you (or your child).

#### RIGHT TO REFUSE

It is your choice to have this testing done on you (your child). If you refuse to have the testing done, you (or your child) will not lose the right to get other health care because of not having results from these

#### WHOM TO CALL IF YOU HAVE OUESTIONS

Please call your doctor if you have any questions about this testing. If you have questions about your (or your child's) rights as a participant in this testing program, please call the CDC Associate Director for Science at 1-800-584-8814. Leave a message with your (or your child's) name, phone number and that the protocol # is 3911. Someone will call you back as soon as possible.

#### CONSENT STATEMENT

I agree that this laboratory testing ca	an be done on samples taken from me	e (my child).
I have read the above and have had	my questions answered by	
Print Patient's Name:		
Patient's/Parent's Signature:		Date:
Legally Authorized Representative Si	gnature :	Date :
Witness to signature: (required by FDA)		Date:
	February 6, 2004	Page 3 of 4

DEPARTMENT OF HEALTH AND HUMAN SERVICES **CENTERS FOR DISEASE CONTROL AND PREVENTION** SAFER · HEALTHIER · PEOPLE"

# Consent Form (SARS Laboratory Testing Public Health Response): Reverse Transcription Polymerase Chain Reaction (RT-PCR) Testing

(continued from previous page) CDC IRB approval as of 2/6/04

#### CONSENT FOR SAMPLE STORAGE

Thank you for agreeing for you (or your child) to be in this program. We are asking for your consent to store any remainders of your (your child's) samples used for SARS virus testing at CDC for future SARS-related investigations. If the results of any future tests are important for your medical care we will make every effort to notify your doctor.

	elated investigations. If the results of any future tests are important for your medical cal se every effort to notify your doctor.	re we
	not do human genetic testing or HIV testing unless we contact you and ask for your consee to storage and change your mind later please call Dr. Dean Erdman at 404-639-3727	
□ Y	es, I agree to long-term storage of my (my child's) samples for future testing	
□ N	No, I do not agree to long-term storage of my (my child's) samples for future testing	
Print Pat	tient's Name:	
Patient's	s/Parent's Signature:	
	Authorized Representative re :	
Date:		
COPY TO	O THE PATIENT.	
	February 6, 2004	Page 4 of 4

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
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### SEVERE ACUTE RESPIRATORY SYNDROME

### CONSENT FORM (SARS-CoV EIA Laboratory Testing)

[Please send a signed copy of this form with the specimen]

The Centers for Disease Control and Prevention (CDC) and public health laboratories are using an investigational laboratory test to test for the virus that causes "severe acute respiratory syndrome" or (SARS). The Food and Drug Administration (FDA) has not licensed this test. The FDA has agreed that we can use this test as part of the public health response to SARS. We do not know for sure if this test can find all people who may get sick with SARS. There are no FDA approved tests that quickly find the virus.

Your State or Local Health Department and CDC are using the results of this test as one piece of information to help us find out if people are sick with SARS and to limit the spread of this illness. Your (or your child's) doctor will use other information along with this test result to decide what is best for you (your child).

#### BACKGROUND

SARS is a respiratory illness that can start as fever and cough. It may go on to pneumonia in some people. SARS seems to be spread by close person to person contact. This can occur when a person who is sick with SARS coughs or sneezes onto themselves, other people, or nearby surfaces. Droplets from the cough or sneeze can travel a short distance through the air and land on the mouth, nose, or eyes of persons who are nearby. The virus also can spread when a person touches a surface or object with infectious droplets and then touches his or her mouth, nose, or eye(s). It also is possible that SARS can be spread through the air or by other ways that we don't yet know about.

#### WHY SHOULD MY (MY CHILD'S) SAMPLE BE TESTED?

You (or your child) may be asked to have SARS testing done when there are no reported cases of SARS in the world or when and if SARS returns. It is important to test for SARS when there are no reported SARS cases so that public health efforts could quickly identify a case and limit its spread. The results of this test, along with other information, may also help your (your child's) doctor take better care of you (your child). You (or your child) may be asked to be tested for the SARS virus because:

- You (or your child) are being hospitalized for symptoms like pneumonia and within 10 days of the start of symptoms you (or your child):
  - a. Have traveled to an area that had reported SARS cases in the past, or
  - b. Had close contact with an ill person who just came back from these areas, or
  - Had close contact with person(s) who have pneumonia like symptoms and have not been diagnosed, or
  - d. Are employed in a job that may put you at risk for SARS, such as a healthcare worker with direct patient contact or a worker in a laboratory that has live SARS virus.

### OR

- There are reported cases of SARS in the world and you (or your child) have symptoms which may be early symptoms of SARS, such as fever or lower respiratory symptoms or other symptoms your doctor feels might be SARS and:
  - a. Recent close contact with persons thought to have SARS, or
  - Recent exposure to areas (in the U.S. or outside the U.S.) with confirmed or suspected SARS (or close contact with ill persons with a history of these exposures)

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#### CONSENT FORM (SARS-CoV EIA Laboratory Testing)

(continued from previous page)

#### ARE THERE ANY BENEFITS?

There may be no direct benefits to you (or your child) from having this test done. This test may help to find the virus in people who do not yet have all the signs of SARS. If people with the SARS virus limit contact with other people, this can prevent others from getting sick. By having this test done, you may lower the chance of spreading the virus from you (your child) to your family or others. Use of this test could also help us to know more about this virus to help stop the spread of this illness. The results of this test, along with other information, may help your (your child's) doctor take better care of you (your child).

## IF THIS TEST IS POSITIVE, DOES THAT MEAN I (MY CHILD) HAVE SARS AND WHAT ARE THE RISKS OF A POSITIVE RESULT?

There is a small chance that this test may give a positive result for the SARS virus when the virus is not there (false positive). If your (your child's) result from this test is positive:

- You (your child) could be asked to limit contact outside the home by not going to work, school, out-of-home childcare, church, or other public areas. You may also be asked to use a mask at home to limit the risk of spread of the virus. If you (your child) have had symptoms of SARS, you might be asked to follow these limits because of these symptoms and not because of the test results. If your (your child's) tests are positive, there is a small chance that you (your child) may be asked to follow these limits even if you (your child) do not seem sick.
- There is no proven treatment for SARS at this time. If you (your child) your child is very ill, in rare cases, you (your child) may be advised to take an antiviral drug. If this happens, your (your child's) doctor will discuss the risks and benefits and obtain your consent.
- 3. Your (or your child's) doctor may decide how to care for you based on the test results along with other factors.

#### IF THIS TEST IS NEGATIVE, DOES THAT MEAN I (MY CHILD) DO NOT HAVE SARS?

This test may give a negative result when you (or your child) actually have the virus (false negative). A false negative result should not have an effect on your (or your child's) care. CDC has told doctors that a negative test does not prove that a person does or does not have the SARS virus. No changes in your medical care or how you interact with people around you should be based on a negative result.

#### ARE THERE ANY RISKS FROM TAKING MY (MY CHILD'S) SAMPLES?

To do this test, extra blood samples may be taken that are like samples that are normally taken for testing when you are sick. Your (your child's) doctor may also ask to take more blood samples in the future.

To do this test, we need a minimum of ¼ teaspoon of blood from children and 1 to 2 teaspoons of blood from adults. This blood may be taken by putting a needle into a vein in your (or your child's) arm. This test may also be done on blood that is left over after other tests for your (your child's) care are done. We may also ask for a second blood sample more than 28 days after you (your child) became sick. We may ask for this second sample in order to test for SARS. This is because this test looks for evidence that the body is fighting the infection (antibodies), and sometimes it takes time for the body to make antibodies to fight the virus.

When we take you (your child's) blood, the needle poke may pinch or sting or cause a bruise.

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#### CONSENT FORM (SARS-CoV EIA Laboratory Testing)

(continued from previous page)

#### ARE THERE OTHER CHOICES?

There are no rapid laboratory tests approved by FDA that can be used to tell if you (or your child) have the virus believed to be causing SARS.

#### WHAT ABOUT PRIVACY?

We will keep all facts about you (your child) as private as the law allows. CDC, FDA the Local/State Health Department staff, and the person(s) who ordered your test (such as your doctor) may see your/your child's results. When we present or publish papers about these tests, neither you (nor your child) will be named.

#### WHAT ARE THE COSTS?

The test will be done by CDC or your health department at no cost. You, your insurer, Medicare or Medicaid will need to pay for other costs related to the testing, such as doctor's visits.

#### WHAT HAPPENS IF YOU (YOUR CHILD) ARE HARMED?

If you (your child) are harmed as a result of taking the samples, CDC will not pay the costs for hospital and medical care. You, your insurer, Medicare or Medicaid will need to pay those costs. You (or your child) do not give up any legal rights that otherwise would be available to you (or your child).

#### RIGHT TO REFUSE

It is your choice to have this testing done on you (your child). If you refuse to have the testing done, you (or your child) will not lose the right to get health care because of not having results from these tests.

#### WHO TO CALL IF YOU HAVE QUESTIONS

Please call your doctor if you have any questions about this testing. If you have questions about your (or your child's) rights as a participant in this testing program or if you feel you have been harmed or injured by taking part in the program, please call the CDC Associate Director for Science at 1-800-584-8814. Leave a message including your (or your child's) name, phone number and that the protocol # is 3918. Someone will call you back as soon as possible.

#### CONSENT STATEMENT

I agree that this laboratory testing can be done on samples collected from me (my cl	nild).
I have read the above and have had my questions answered by	·
Print Patients Name:	
Patient's/Parent's Signature:	Date:
Legally Authorized Representative Signature :	Date :
Witness to signature:(required by FDA)	Date:

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### CONSENT FORM (SARS-CoV EIA Laboratory Testing)

(continued from previous page)

<u>CONSENT FOR SAMPLE STORAGE</u>
Thank you for agreeing for you (or your child) to be in this program. We are asking for your consent to store any remainders of your (your child's) samples used for SARS virus testing at CDC for future SARSrelated research. If the results of any future tests are important for your medical care we will make every effort to notify your doctor.

We will not do human genetic testing or HIV testing unless we contact you and ask for your consent. If you agree to storage and change your mind later please call Dr. Lia Haynes at 404-639-4004.

Yes, I agree to long-term storage of my (my child's) samples for future testing		
No, I do not agree to long-term storage of my (my child's) samples	for future testing	
Print Patient's Name:		
Patient's/Parent's Signature:		
Legally Authorized Representative Signature :	_	
Date:		
NOTE: PLEASE INCLUDE A SIGNED COPY OF THIS FORM WITH T COPY TO THE PATIENT.	HE SPECIMEN AND PROVIDE A	
For more information, visit <a href="www.cdc.gov/ncidod/sars">www.cdc.gov/ncidod/sars</a> or call the at (888) 246-2675 (English), (888) 246-2857 (Español), or	CDC public response hotline (866) 874-2646 (TTY)	

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